

KLEPINSKI & DUVAL

ROBERT J. KLEPINSKI
MARK E. DUVAL

Klepinski & DuVal, PA
3902 IDS Center
80 South 8th Street
Minneapolis, MN 55402
612-338-7170 Phone
612-843-2398 Fax
www.klepinski-duval.com

October 20, 2004

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: Draft Guidance Document on Custom Devices

Dockets Management Branch:

Enclosed is a draft guidance document that I am submitting to Dockets Management on behalf of AGA Medical Corporation. I am submitting the guidance, "Draft Guidance, Custom Devices," for filing pursuant to 21 CFR 10.20.

I have enclosed four copies of the guidance as required. I also have sent courtesy copies of the draft guidance to several people in CDRH. Please contact me with any questions. Thank you.

Regards,



Robert J. Klepinski

Enclosure

cc: Anne Hawthorne
Harold Pellerite
Philip Phillips
Casper Uldriks
Daniel Schultz

2004 D. 0476

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